STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

Xolair® (Omalizumab)

Effective 09/27/2018

Prior Authorization Request Form

Xolair is an anti-IgE antibody indicated for:

- *Moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids.*
- *Chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.*

Prior authorization requests for Xolair may be approved if the following criteria are met:

For moderate to severe persistent asthma

1) Patient is six (6) years of age or older; **AND**
2) Must be prescribed by a board-certified pulmonologist or board-certified allergist; **AND**
3) Current body weight is between 20kg and 150kg; **AND**
4) If the patient currently smokes they must be enrolled in a smoking cessation program; **AND**
5) Patient is symptomatic despite receiving recommended first line treatments (including high dose inhaled corticosteroids + LABA) and exhibiting compliance with those treatments; **AND**
6) Patient has reacted positively to a perennial aeroallergen skin or blood test; **AND**
7) Patient must have an IgE level not less than 30 IU/ml or more than the Manufacturer's recommendation, based on weight. (The patient's weight and pretreatment serum IgE must be presented to review dosing).

For moderate to severe Chronic Idiopathic Urticaria:

1) Current diagnosis must be Chronic Idiopathic Urticaria, (documentation supporting diagnosis must be provided with PA request); **AND**
2) Patient is twelve (12) years of age or older; **AND**
3) Prescribed by a board-certified Allergist, Immunologist, or Dermatologist; **AND**
4) Contraindication to, or documented failure of, scheduled H-1 antihistamine at maximum tolerable dosing***** and leukotriene inhibitor therapy; **AND**
5) Evidence of an evaluation that excludes other medical diagnoses associated with chronic urticaria (supporting documentation must be provided with PA request).

* For CIU, intolerance/contraindication to maximum dosing of H-1 antihistamine must be clearly documented and justified on the prior authorization request. As-needed or "burst" therapies will not be considered as adequate therapy attempts.

Prior authorization requests for will be initially granted for three (3) months. Prior authorization will be granted for an additional twelve (12) months after receipt of documentation supporting clinical improvement from prior to initiating omalizumab.

References:

1) Xolair® (package insert) Genentech Inc. South San Francisco, CA. 5/2018
2) Lexi-Comp™ Xolair monograph and Clinical Consult™ application 9/182018.
3) Asthma Care – Guidelines from the National Asthma Education and Prevention Program (2012)
4) Global Initiative for Asthma – 2018 guidelines